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 64 Plaintiff NATERA, INC.

65 GUARDANT HEALTH, INC.,

66 Plaintiff and Counterclaim-
 67 Defendant,

68 vs.

69 NATERA, INC.,

70 Defendant and Counterclaim-
 71 Plaintiff.

72 Case No. 3:21-cv-04062-EMC

73 **JOINT SUBMISSION RE OBJECTIONS
 74 REGARDING OPENINGS (Dkt. 751)**

1 **Guardant's Position on Natera's Opening Slides**

2 Pursuant to this Court's Order, Dkt. 751 (October 25, 2024), Guardant raises the following
 3 Objections to Natera's Opening demonstratives.

4 The Parties exchanged their proposed presentations for Opening statements at 4:00 on
 5 Sunday, November 3, 2024. The Parties then exchanged objections, and met and conferred.
 6 Following the conference, the Parties agreed to withdrew certain exhibits that had been the subject
 7 of objections. According, Guardant objects to only three of Natera's demonstratives, including:¹

8 **TX-585.** Natera has represented that it intends to use Slide No. 7 of this November 12,
 9 2020 Guardant presentation entitled "Guardant Health New Product Introduction." The slide is
 10 directed to explaining why Guardant should obtain Local Coverage Decision approval (that is,
 11 Medicare coverage) from MolDX for Reveal. As required by MolDX rules and regulations,
 12 Guardant's document compares the performance of Guardant's Reveal in the Parikh Study to the
 13 performance of Natera's Signatera (the then MolDX LCD holder) in the Reinert Study across five
 14 metrics (landmark and surveillance sensitivity; specificity; PPV, lead time, and CEA sensitivity
 15 and specificity). In this Court's *in limine* rulings, this Court held that "statements made to MolDX
 16 are not actionable." Dkt. 509 at 3; *see also id.* at 4 (noting that Natera's attacks on Reveal made to
 17 MolDX "were not made directly to potential consumers of Guardant or Natera's colorectal
 18 screening products, or in the paradigmatic advertising context.") Guardant's discussions regarding
 19 its non-advertising efforts to satisfy MolDX's regulatory standards by comparing aspects of the
 20 Parikh and Reinert Studies therefore have no role in this Lanham Act false advertising trial. It is
 21 apparent that Natera is going to use TX-585 to seek to mislead the jury into believing that Guardant
 22 also uses comparative advertising, when in fact it does not and engaged in this performance
 23 comparison to satisfy MolDX's regulatory requirements.. The exhibit is of limited (or no)
 24 relevance, and any relevance is significantly outweighed by the undue prejudice use of the

25 ¹ Based on representations made by Natera's counsel during the Parties' meet and confer, Guardant
 26 does not object to Natera's plan to use pages 35, 36, and 37 of TX-598. Similarly based on
 27 counsel's representations, Guardant does not object to Natera's use of TX-1259 and TX-1268,
 28 peer-reviewed articles concerning Signatera used for breast and lung cancer, to the extent they are
 used only to show that Natera has peer-reviewed publications involving use in these different
 cancer types.

1 document would entail. Natera should be instructed to not use this irrelevant exhibit during its
 2 Opening.

3 **TX-1786 & TX-1787:** The first of these exhibits is a very recent article authored by Dr.
 4 Parikh involving Reveal as used with patients with oligometastatic CRC (a notoriously difficult
 5 form of cancer), while the second is a series of figures drawn from the study. Published on July
 6 15, 2024 in the journal Clinical Cancer Research, the article post-dates the March 2024 “cut-off”
 7 imposed by this Court’s sanctions ruling. *See* Dkt. 719. Moreover, Natera’s counsel’s has refused
 8 to state for what purpose this article will be used during the Opening. Dr. Parikh is no longer an
 9 expert witness in this case, and we are not aware of any relevance for either the article or the figures
 10 drawn from it. Accordingly, the Court should preclude use of an apparently irrelevance article that
 11 post-dates this Court’s restrictions on evidence.

12 **Response to Natera’s objections to Guardant’s opening.** By contrast to Guardant’s
 13 restraint, Natera has indicated that it intends to object to virtually all of Guardant’s Opening,
 14 notwithstanding Guardant’s accommodation to Natera’s objections. In initial exchanges of
 15 objections, Natera claimed that about two-thirds of Guardant’s presentation was “Argumentative
 16 and Misleading/False.” Because the Parties have not exchanged their separate portions of this
 17 submission in advance, it is unclear which objections Natera will stand on.

18 One of the objections Natera raised is that Guardant will be playing short clips of deposition
 19 testimony. To be clear, Guardant is *not* going to offer deposition testimony in lieu of live
 20 testimony—it intends to question Natera’s witnesses live. Natera also raised objections with
 21 respect to any mention of Dr. Claus Lindbjerg Andersen’s deposition, and separately filed a motion
 22 to preclude use of his testimony. Guardant is separately responding to Natera’s objections
 23 regarding the deposition transcripts for Dr. Andersen.

24 Natera improperly objects to a number of Guardant’s slides based on this Court’s ruling on
 25 Natera’s MIL No. 2, Dkt. 509. However, this Court’s ruling allows Guardant’s use of evidence
 26 regarding Natera’s statements to and about MolDX “for the purpose of showing Natera’s state of
 27 mind at the time it launched its advertising campaign.” *Id.* at 9. That is precisely the purpose of
 28 Guardant’s slides. Finally, Natera improperly objects to Guardant’s slides based on this Court’s

1 ruling on Natera's MIL No. 3, but again this Court's ruling allows this evidence for the purpose
2 presented by Guardant: "For example, Guardant points to documents wherein Natera employees
3 described the Reinert study as 'blinded' while Natera employees had access to recurrence
4 information as to patients in the study; this may shed light on the proper meaning of 'blinded' as
5 asserted by Natera." Dkt. 509 at 15.

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1 **I. NATERA'S POSITION ON GUARDANT'S OPENING SLIDES**

2 MolDX Material in Violation of MIL 2. Guardant's opening slides 14, 17, 20, 23, 25, 35,
 3 37, 38, 39, and 59 argue that Natera “[p]ressure[d] Medicare to deny access to Guardant's life-
 4 saving test.” In granting-in-part Natera's MIL 2, the Court held that Guardant's claim that Natera's
 5 statements to MolDX affected any decision by MolDX is barred under FRE 403. Dkt. 509 at 8.
 6 As the Court recognized, this evidence cannot be the basis of liability under the Lanham Act, and
 7 would confuse the jury. Guardant's argument that this all goes to state of mind would allow the
 8 narrow exception in the Court's order to swallow the rule. At a minimum, a limiting instruction
 9 is necessary.

10 Unreliable Andersen Transcripts, also in Violation of Multiple Orders Regarding the
 11 Reinert Study. Guardant's opening slides 4, 13, 28, 36, 41, 43, 45, 48, 65, 72, 73, 75, 76, and 78
 12 improperly present the unofficial, unsworn transcripts of the Danish hearing of the questioning of
 13 Dr. Claus Andersen (“Andersen Hearing”). These transcripts are inadmissible pursuant to FRE
 14 403, 604 and 901. *See* Dkt. 763. First, the transcripts do not reflect a verbatim transcript of Dr.
 15 Andersen's statements and, instead, were a transcript of Guardant's interpreter's simultaneous and
 16 uncertified translations. Second, the interpreter was not under oath and, therefore, the transcripts
 17 are inadmissible under FRE 604. Finally, Guardant did not provide any certification the translation
 18 was true and correct, and so are inadmissible under Rule 901.

19 Guardant also cannot circumvent the Court's orders excluding this evidence. First, on
 20 summary judgment, the Court excluded Guardant's affirmative defense of unclean hands based on
 21 allegations that “Natera engaged in inequitable conduct in the Reinert study.” Dkt. 329-2 at 42.
 22 Second, on the parties' motions *in limine*, the Court held that evidence of the Reinert Study can
 23 only be used for a very limited purpose: “to shed light on the meaning of ‘prospective’ and
 24 ‘blinded’ — which are the subject of Natera's counter-claims against Guardant (asserting the
 25 Parikh study is fraudulent because those terms were mischaracterized)” Dkt. 509 at 15 (“This
 26 evidence may be admitted for impeachment purposes only”). Finally, the Court excluded
 27 certain emails related to the Reinert Study as irrelevant because Guardant's claims against Natera
 28 are unrelated to the validity of the Reinert Study. Dkt. 611 at 14-15.

1 Guardant Cannot Play Deposition Testimony of Live Witnesses. Guardant's opening
 2 slides 19, 31, 45, 56, 58, 61, 68, 70, 71, and 74 present excerpted deposition testimony from several
 3 witnesses who are appearing live for trial, including Guardant's own witness Ms. Rich. This
 4 violates the Court's ruling on deposition testimony for live witnesses (Dkt. 751), as well as FRE
 5 106 and 403, and backtracks on Guardant's prior representations. The Court noted that "Guardant
 6 stated they did not plan to use deposition testimony for live witnesses outside of impeachment
 7 purposes." Dkt. 751 at 2:22-23. Guardant represented that it "will not present adverse witnesses
 8 by deposition if they appear live at trial." Dkt. 720 at 2. Guardant objected to exactly this practice.
 9 See Oct. 15, 2024 Tr. at 176:9-12, 178:4-6, 179:21-23.

10 Argumentative, Misleading, and/or False Headings and Content. Guardant's slides 2, 4,
 11 5, 7, 8, 9, 10, 11, 12, 13, 14, 16, 17, 20, 21, 22, 24, 25, 26, 27, 28, 30, 33, 34, 35, 40, 42, 44, 46,
 12 47, 48, 49, 51, 52, 53, 55, 57, 58, 59, 61, 62, 64, 65, 67, 71, 72, 73, 74, 75, 76, 77, and 79 are
 13 argumentative, false, and/or misleading. *See U.S. v. Dinitz*, 424 U.S. 600, 612 (1976) (Burger,
 14 C.J., concurring) (purpose of opening "is to state what evidence will be presented . . . ; it is not
 15 an occasion for argument"); *See Engineered Floors, LLC v. Lakeshore Equip.*, 2024 WL 891796,
 16 at *1 (C.D. Cal. Feb. 15, 2024) (similar). Guardant's opening includes argumentative statements
 17 such as "Bombard cancer doctors with false advertisements," "Pressure Medicare to deny access
 18 to Guardant's life-saving test," "Natera Panicked," and "Natera's War." Guardant also includes
 19 false statements in its slides, such as "Guardant's Reveal Can Be Used By All Cancer Patients,"
 20 "Medicare Approved Reveal as Equivalent or Superior to Signatera," "Danish Study: ... Used
 21 another test (not Signatera) to boost performance," and "Signatera at Post-Operative – Detects
 22 Cancer (Sensitivity) Less Than Half the Time."

23 Additional Objections. Natera maintains its objections to Guardant's use of TX 41 (FRE
 24 105, 403, Dkt. 611 at 11), and TX 156 and 227 (105, Natera MIL 2). Natera objects to slide 7
 25 because it contains incomplete, partial answers; slides 47 and because they lack foundation and
 26 are hearsay; slides 16, 50, 63, 66 and 79 under FRE 402 and 403; slides 34 and 41 as excluded
 27 under MIL 3 (Dkt. 509 at 14-15); and slide 77 because it contains undisclosed expert testimony.

1 **II. NATERA'S RESPONSES TO GUARDANT'S OBJECTIONS**

2 TX-585 is a Guardant document in which Guardant directly compares Signatera and
3 Reveal, and the Reinert and Parikh studies, in a presentation submitted to MolDx. It is directly
4 relevant to Guardant's central claim that comparing Signatera and Reveal, and the Reinert and
5 Parikh studies, is a misleading "apples-to-oranges" comparison. Guardant cannot seek to exclude
6 evidence of its own comparisons between the Reinert and Parikh studies while claiming Natera's
7 comparisons are misleading. Nor is TX-585 barred by the Court's ruling on Natera's MIL 2,
8 which related to Natera's communications with MolDx—not Guardant's. In any event, the
9 Court ruled that those communications with MolDx were relevant to show state of mind, and
10 Guardant references Natera's communications with MolDx throughout its opening
11 demonstratives.

12 TX-1786 (a publication) and TX-1787 (accompanying supplementary data) are not
13 subject to the Court's Order (Dkt. 730), which issued a sanction in the form of "excluding
14 COBRA in its entirety, Dr. Hochster's supplemental report on COBRA, and other discovery
15 flowing from COBRA." The Court "turn[ed] back the clock on this issue" but did not exclude
16 all facts that have arisen in the interim. Neither of these exhibits mention COBRA. The
17 publication (TX-1786) states that it was received on November 28, 2023, months before the
18 Court's cutoff. It was co-authored by several Guardant witnesses who will testify at trial, was
19 co-authored by Drs. Corcoran and Parikh, and is relevant to Reveal and the 2021 Parikh study.

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1 As to Guardant's Positions:

2 Dated: November 3, 2024

A&O SHEARMAN

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4 By: /s/ Saul Perloff
Saul Perloff

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6 Attorney for Plaintiff/Counter-Defendant
7 GUARDANT HEALTH, INC.

8 As to Natera's Positions:

9 DATED: November 4, 2024

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FILER'S ATTESTATION

Pursuant to Civil LR 5.1(i)(3), the undersigned hereby attests that concurrence in the filing of this **JOINT SUBMISSION RE CROSS-OBJECTIONS TO OPENINGS** has been obtained from counsel for Natera, Inc. and is electronically signed with the express permission of Natera's counsel.

Date: November 3, 2024

By: /s/Saul Perloff
Saul Perloff

Attorney for Plaintiff/Counter-Defendant
GUARDANT HEALTH, INC.

1 **CERTIFICATE OF SERVICE**

2 In accordance with Local Rule 5-5, I certify, that on November 4, 2024, this document,
3 filed with the Court through the CM/ECF system, will be sent electronically to the registered
4 participants at their e-mail addresses as identified in the Notice of Electronic Filing (NEF). Non-
5 CM/ECF participants will be served via First-Class Mail.

6 I certify under penalty of perjury that the foregoing is true and correct. Executed this 3rd
7 day of November.

8 _____
9 _____
Saul Perloff

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